UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

ROBERT DOUSTOU Plaintiff, v. ATRIUM MEDICAL CORPORATION, MAQUET CARDIOVASCULAR US SALES, LLC; and GETINGE AB Defendants.	)	Civil Action No.: _____ COMPLAINT AND JURY DEMAND

Plaintiff, Robert Doustou ("Plaintiff"), by and through his undersigned attorneys, brings this Complaint for damages against Atrium Medical Corporation, Maquet Cardiovascular US Sales, LLC and Getinge AB (hereafter collectively as "Defendants") and in support thereof states the following:

1. This is a medical device tort action brought on behalf of the above-named Plaintiff arising out of the failure of Defendants' C-Qur hernia mesh product. As a result, Plaintiff Robert Doustou suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. The Plaintiff respectfully seeks all damages to which he may be legally entitled.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and all Defendants.

3. Venue is proper in this Court pursuant to 28 U.S.C. §1332(a)-(c) by virtue of the

facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in and (b) Defendants' products are produced, sold to, used and consumed by individuals in the State of Maine, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this District.

4. Defendants have and continue to conduct substantial business in the State of Maine and in this District, distribute Hernia Mesh Products in this District, receive substantial compensation and profits from sales of Hernia Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

5. Defendants conducted business in the State of Maine through sales representatives conducting business in the State of Maine and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, and/or through third parties or related entities, Hernia Mesh Products in Maine.

6. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Maine, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

TAG ALONG ACTION

7. This is a potential tag-along action and, in accordance with 28 U.S.C. § 1407, it should be transferred to the United States District Court for the District of New Hampshire for inclusion in *In re: Atrium Medical Corp. C-Qur Mesh Products Liability Litigation*, MDL No. 2753 (Hon. Landya B. McCafferty).

PARTIES

8. Plaintiff Robert Doustou ("Plaintiff") is a citizen and resident of Poland, Maine.

9. Atrium Medical Corporation ("Atrium") is incorporated under the laws of Delaware and, at all pertinent times, Atrium's principal place of business was located in Hudson, New Hampshire. Atrium is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including C-QUR Mesh (hereinafter "C-QUR" or "product" or "mesh").

10. Maquet Cardiovascular US Sales, LLC ("Maquet") is a limited liability company organized under the laws of New Jersey, with its principal place of business located at 45 Barbour Pond Drive, Wayne, NJ 07470. At all times pertinent hereto, Atrium has operated within, and as a business unit of, Maquet. Following reasonable inquiry and diligent search, upon information and belief, each of the LLC Members of Maquet is a citizen of a state other than Maine.

11. Getinge AB ("Getinge") is a Swedish corporation, organized under the laws of Sweden with its principal place of business in Sweden. At all times pertinent hereto, Maquet and Atrium were a wholly-owned subsidiaries of Getinge AB.

12. Getinge is a holding company the purpose of which is to coordinate the administration, finances and activities of its subsidiary companies, including Maquet and its business unit/division Atrium, and to act as managers and to direct or coordinate the management of its subsidiary companies or of the business, property and estates of any subsidiary company, including Maquet and its business unit/division Atrium.

13. The financial accounts of Maquet and its business unit/division Atrium are consolidated within those of Getinge.

14. In 2011, Getinge acquired Atrium through a merger. When Getinge acquired Atrium through the merger, it acquired Atrium's assets and assumed Atrium's liabilities.

15. Since the merger, Atrium has operated as a division/business unit of Getinge subsidiary Maquet.

16. Getinge is the owner of 100% of the controlling shares of Atrium stock and assets, including the rights to Atrium's C-QUR patents. Maquet has direct control over Atrium's activities. Following the merger with Atrium, Getinge and Maquet have continued to manufacture and sell the same defective C-QUR product line as Atrium under the same brand so as to hold themselves out to the public as a continuation of Atrium and benefit from Atrium's brand and goodwill. The Maquet Getinge Group website (www.maquet.com) lists the C-QUR product as one of Maquet Getinge Group's "biosurgery" products. (http://www.maquet.com/us/products/C-QUR-mesh/?ccid=231).

17. Defendants Getinge and Maquet represent that Atrium had become "part of 'Maquet Getinge Group.'" See http://www.atriummed.com (stating that "Atrium is now part of Maquet Getinge Group"); http://www.atriummed.com/News/atriumnews.asp?articleid=60&zoneid=1 (press release detailing the acquisition of Atrium by Maquet Getinge Group).

18. Getinge and Maquet are liable for any acts and/or omissions by or through Atrium. Following the merger, which occurred prior to the sale to and implantation of the C-QUR mesh into Plaintiff Robert Doustou, Atrium was so organized and controlled and its business conducted in such manner as to make it merely an alter ego or business conduit of Getinge and Maquet. Because Atrium's assets and capital are subject to the ownership and control of Maquet and Getinge, Atrium is undercapitalized and the failure to disregard Atrium's

corporate form would result in the inequitable and unjust result that Plaintiff may be unable to satisfy any judgment ultimately obtained against Atrium. Atrium acts as agent for Getinge and Maquet. Maquet, Getinge and Atrium combine their property and labor in a joint undertaking for profit, with rights of mutual control.

19. Maquet and Getinge, directly and/or through the actions of their Atrium division and business unit, have at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of C-QUR Mesh.

20. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective mesh products at issue in the instant suit, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

21. Defendants are vicariously liable for the acts and/or omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

DEFENDANTS' HERNIA MESH PRODUCTS

22. Defendants' Hernia Mesh Products were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

23. Defendants' Products contain polypropylene mesh. Despite claims that this material is inert, a substantial body of scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes and immune response in a large subset

of the population receiving Defendants' Products. This immune response promotes degradation of the polypropylene mesh, which can contribute to severe adverse reactions to the mesh.

24. Defendants' polypropylene-based Hernia Mesh Products are designed, intended, and utilized for permanent implantation into the human body.

25. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the known severe risks associated with polypropylene.

26. Upon information and belief, Defendants' use adulterated polypropylene in their Hernia Mesh Products.

27. Defendants' failed to warn or notify doctors, including Plaintiff's implanting surgeon, regulatory agencies, and consumers of the Defendants' use of adulterated polypropylene in their Hernia Mesh Products.

28. Defendants' C-Qur Mesh utilizes a blend of Omega 3 Fatty Acid Fish Oil ("O3FA") to form a barrier coating on its C-Qur Mesh.

29. The O3FA is derived from fish. Fish derivatives are considered to be commonly allergenic and immunogenic. If various remnants of the fish – such as proteins, genetic material, or adjuvant compounds – remain in the O3FA coating, an immune response can occur, causing complications including but not limited to pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

30. Proteins are not very soluble in oils; however, non-soluble proteins may remain in the oil as particulate matter.

31. Upon information and belief, Defendants' failed to adequately test, inspect, and/or

verify that each supplied batch of O3FA was free from proteins, genetic material, and adjuvant compounds.

32. Upon information and belief, Defendants' utilized adulterated O3FA in the production of the C-Qur Mesh.

33. Upon information and belief, Defendants' utilized plasticizers and other toxic additives on the O3FA in the production of the C-Qur Mesh.

34. Upon receiving reports from surgeons and physicians of apparent allergic reactions to the C-Qur Mesh, Defendants misled physicians about the ability and tendency of O3FA to cause allergic reactions in patients implanted with a C-Qur Mesh and attempted to convince the physicians of alternate causes. Defendants' intentionally, or at very least, recklessly disregarded human life by lying to physicians about the possible causes of the allergic reaction, resulting in significantly more severe injuries in those already implanted with the C-Qur Mesh, and more patients nationwide being implanted with the C-Qur Mesh.

35. Upon information and belief, Defendants' changed the way in which they handled and/or applied the O3FA coating to the C-Qur Mesh. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety.

36. Upon information and belief, Defendants' utilized non-conforming goods in the production of the C-Qur Mesh, including accepting goods without the required documentation to verify the source, quality, authenticity, or chain of custody of the goods.

37. Upon information and belief, the O3FA component of Defendants' C-Qur Mesh is cytotoxic, immunogenic, and not biocompatible, resulting in complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and death.

38. Upon information and belief, Defendants had actual knowledge of the cytotoxic and immunogenic properties of the O3FA component of the C-Qur Mesh prior to introducing it into the stream of commerce.

39. Defendants failed to adequately test the effects of the known cytotoxicity of the C-Qur Mesh in animals and humans, both before and after the product entered the stream of commerce.

40. Defendants' failed to warn or notify doctor, regulatory agencies, and consumers of the cytotoxicity of the C-Qur Mesh.

41. Defendants utilize Ethylene Oxide ("ETO") in an attempt to sterilize the C-Qur Mesh. ETO is an effective disinfectant; however, dry spores are highly resistant to ETO. Moisture must be present to eliminate spores using ETO. Presoaking the product to be sterilized is most desirable, but high levels of humidity during the ETO process can also be effective in eliminating spores. C-Qur Mesh implanted with spores will result in an infection. The spores can remain dormant for extended periods of time, resulting in infections months or years after implantation with the C-Qur Mesh.

42. Moisture and high humidity levels are contraindicated for the C-Qur Mesh, as it will result in the O3FA coating peeling off the polypropylene and/or sticking to the packaging.

43. Defendants' use of ETO on the C-Qur Mesh results in:

a. High infection rates due to inadequate moisture during the ETO cycle; and/or

b. O3FA coating peeling off the polypropylene due to moisture.

44. Defendants failed to warn or instruct distributors and facilities of critical

environmental guidelines, such as relative humidity or temperature during transportation and/or storage of the C-Qur Mesh. The environmental guidelines for the C-Qur Mesh are unique to the C-Qur Mesh and are not necessary for other similar or competing hernia mesh products. Excess temperature and/or humidity result in the C-Qur Mesh degrading and transforming into an even more dangerous product.

45. Defendants failed to conduct adequate testing to determine the proper environmental guidelines for storage and transportation of the C-Qur Mesh prior to introducing it into the stream of commerce.

46. ETO is ineffective at sterilizing the C-Qur Mesh due the O3FA coating, multiple layers of the mesh, and mated surfaces of the C-Qur Mesh.

47. Defendants' changed the process of their ETO sterilization cycle without performing adequate testing or verification of sterility, or other effects the changes might have had on the product. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety.

48. Upon information and belief, Defendants utilized a package that allowed humidity levels to fluctuate to unacceptably high levels within the package.

49. Upon information and belief, Defendants utilized a packaging material that promoted the O3FA coating to adhere to the packaging of the C-Qur Mesh.

50. Upon information and belief, Defendants manufactured the C-Qur Mesh in a way that promoted that O3FA coating to adhere to the packaging of the C-Qur Mesh.

51. Defendants failed to properly warn physicians, regulatory agencies, and

consumers of the risk associated with the O3FA coating adhering to the package. Defendants' assured physicians and regulatory agencies that the C-Qur Mesh was still fit for human implantation, even if some or all of the O3FA coating had been pulled away.

52. Once the O3FA coating has started or shown propensity to detach from the polypropylene, it is much more likely that the O3FA coating will detach from the polypropylene once implanted. If the O3FA coating detaches once implanted, it can float in the body or ball up, causing an even more intense foreign body reaction, resulting in rejection and other complications of the C-Qur Mesh. Detachment of the O3FA coating also greatly increases the risk of the C-Qur Mesh adhering to the patients underlying organs, resulting in significantly more difficult and complex surgeries to remove the mesh. Due to the C-Qur Mesh adhering to the underlying organs, patients experience significant, life-changing injuries, prolonged hospital stays, and even death.

53. The O3FA coating on both sides of the C-Qur Mesh prevents adequate tissue incorporation and ingrowth, which causes or contributes to excessive scarification and encapsulation of the device after implantation.

54. The known and intended degradation of the O3FA coating allows the uncoated polypropylene mesh to directly contact adjacent organs which causes or contributes to adhesion to the organs, erosion, infection, abscess and fistula formation.

55. Defendants were and are currently aware of the life-threatening complications associated with the O3FA coating peeling off inside of patients.

56. Defendants encouraged physicians to implant C-Qur Mesh in which the O3FA coating had peeled away from the polypropylene and was stuck to the packaging.

57. Defendants' encouragement of physicians to implant C-Qur Mesh in which the

O3FA coating had adhered to the packaging and was no longer present on the polypropylene was an intentional, or at very least, a reckless disregard of human life.

58. Defendants changed the way in which the C-Qur Mesh is packaged. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety.

59. Upon information and belief, at relevant times, Defendants modified the processing temperature and processing speed of one or more steps in the manufacturing process. This change in the manufacturing process was a deviation from the initial design and was carried out without first conducting tests to determine the effect of the change on patient safety.

60. Upon information and belief, Defendants adjusted the threshold for reporting and recalling the C-Qur Mesh due to nonconformities and adverse event reports when the threshold was met, resulting in a large number of injurious events that were deemed by the Defendants to be "acceptable" and went unreported as a result and unrecalled.

61. Upon information and belief, Defendants manipulated, altered, skewed, slanted, misrepresented, and/or falsified pre-clinical and/or clinical studies to bolster the perceived performance of the C-Qur Mesh.

62. Upon information and belief, Defendants paid researchers, doctors, clinicians, study designers, authors, and/or scientist to study the effectiveness of the C-Qur Mesh, but did not disclose these relationships in the studies themselves.

63. Upon information and belief, Defendants' paid doctors, surgeons, physicians, and/or clinicians to promote the C-Qur Mesh, but did not readily disclose this information.

64. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events.

65. Defendants failed to employ an adequate number of staff to receive, process, investigate, document, and report adverse events.

66. Defendants "stealth recalled" multiple types of C-Qur Mesh that were experiencing high levels of adverse events, by simply halting production of multiple types of C-Qur Mesh without notifying physicians, or consumers of the recall or high levels of adverse events.

67. Defendants failed to implement adequate procedures and policies to detect the presence of foreign materials in or on the C-Qur Mesh.

68. Defendants failed to implement adequate procedures and policies to prevent C-Qur Mesh with known foreign materials from entering the stream of commerce.

69. Defendants failed to design a method or process that ensures conformity in the amount of O3FA applied to each type of C-Qur Mesh.

70. Defendants failed to warn or instruct physicians on the proper and/or contraindicated methods of securing and/or implanting the C-Qur Mesh. Defendants blamed physicians' methods of implantation and securing the C-Qur Mesh when complications known by the Defendants to be caused by a defect in the C-Qur Mesh were reported by physicians.

71. Defendants marketed the C-Qur Mesh to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants have made claims that the C-Qur Mesh is superior in a variety of ways, but have never conducted a single clinical study on the C-Qur Mesh implanted in humans. Defendants' deception through false advertising resulted in more physicians utilizing the C-Qur Mesh.

72. Defendants marketed and sold the C-QUR Mesh Products to the medical

community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, and private offices, and include the provision of valuable benefits to health care providers. Also utilized were documents, patient brochures, and websites.

73. For years the Defendants have been notified and warned about the widespread catastrophic complications associated with the C-Qur Mesh by leading hernia repair specialists, surgeons, hospitals, patients, internal consultants, and employees. However, not a single C-Qur Mesh has been formally recalled from the market. Defendants have misrepresented the efficacy and safety of the C-Qur Mesh, through various means and media, actively and intentionally misleading the medical community, patients, and the public at large.

74. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' C-Qur Mesh.

75. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' C-Qur Mesh; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' C-Qur Mesh.

76. Feasible and suitable alternative procedures and instruments, as well as suitable alternative designs for implantation and treatment of hernias and soft tissue repair have existed at all times relevant as compared to the Defendants' C-Qur Mesh.

77. The Defendants' C-Qur Meshes were at all times utilized and implanted in a manner foreseeable to the Defendants.

78. The Defendants have at all times provided incomplete, insufficient, and

misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' C-Qur Mesh, and thus increase the sales of the C-Qur Mesh, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

79. The C-Qur Mesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

80. The injuries, conditions, and complications suffered due to Defendants' C-Qur Meshes include but are not limited to foreign body reaction, rashes, infection, adhesions, organ perforation, inflammation, fistula, mesh erosion, scar tissue, blood loss, neuropathic and other acute and chronic nerve damage and pain, abdominal pain, nausea, vomiting, kidney failure, and in many cases the patients have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove the C-Qur Mesh, operations to attempt to repair abdominal organs, tissue, and nerve damage, the use of narcotics for pain control and other medications, and repeat operations to remove various tissues that are contaminated with the C-Qur Mesh.

FACTUAL BACKGROUND

81. On or about October 7, 2014, Plaintiff Robert Doustou underwent a ventral incisional hernia repair with Atrium C-QUR Mesh at Maine Medical Center in Portland, Maine.

82. Defendant, manufactured, sold, and/or distributed the C-QUR Mesh Products to Plaintiff, through his doctors, to be used for treatment of hernia repair.

83. On or about December 10, 2014, Plaintiff presented to Central Maine Medical

Center with complaints of recurrent ventral incisional hernia removal. During the operation, the surgeon found that the C-QUR Mesh had "mostly disintegrated" causing a recurrent hernia and requiring implantation of new mesh.

84. The C-Qur Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use and created procedures for implanting the mesh.

85. Other than any degradation caused by faulty design, manufacturing, or faulty packaging**,** the C-QUR Mesh implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants, and in the condition directed by and expected by Defendant.

86. Plaintiff and his physicians foreseeably used and implanted the C-QUR Mesh Products, and did not misuse, or alter the Products in an unforeseeable manner.

87. Defendants advertised, promoted, marketed, sold, and distributed the C-QUR Mesh Products as a safe medical device when Defendant knew or should have known the C-QUR Mesh Products were not safe for their intended purposes and that the mesh products could cause serious medical problems.

88. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects.

89. In reliance on Defendants' representations, Plaintiff's implanting surgeon was induced to, and did use the C-Qur Mesh.

90. As a direct and proximate result of having the C-Qur Mesh implanted in him, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo

corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

91. Defendants' C-Qur Meshes have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive or open surgical techniques for the treatment of medical conditions, primarily hernia repair and soft tissue repair, and as a safer and more effective as compared to the traditional products and procedures for treatment, and other competing hernia mesh products.

92. The Defendants have marketed and sold the Defendants' C-Qur Meshes to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

93. Plaintiff in the exercise of due diligence, could not have reasonably discovered the cause of his injuries including but not limited to the defective design and/or manufacturing the C-Qur Mesh implanted inside of him until a date within the applicable statute of limitations.

COUNT I
NEGLIGENCE

94. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

95. At all relevant times, Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' C-Qur Mesh, and recruitment and training of physicians to implant the C-Qur Mesh.

96. Defendants breached their duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the C-Qur Mesh.

97. Defendants knew or should have known that its failure to exercise ordinary care in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution and recruitment and training of physicians to implant the C-Qur Mesh would cause foreseeable harm, injuries and damages to individuals such as Plaintiff who are implanted with C-Qur Mesh.

98. As a direct, proximate and foreseeable result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the C-Qur Mesh, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

99. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff.

COUNT II
STRICT LIABILITY – DESIGN DEFECT

100. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

101. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the C-Qur mesh implanted into Plaintiff. The mesh was defective in its design as detailed herein and in that when it left the hands of Defendants, it was not safe for its anticipated use and safer feasible alternative designs existed that could have been utilized by Defendants. A reasonably prudent medical device manufacturer would not have placed the C-Qur mesh with its defective design into the stream of commerce.

102. The C-Qur Mesh was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was implanted in Plaintiff.

103. The C-Qur Mesh was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the mesh were more dangerous than a reasonably prudent consumer such as Plaintiff and/or his physician would expect when the mesh was used for its normal and intended purpose.

104. The C-Qur Mesh reached Plaintiff's implanting surgeon and was implanted in Plaintiff without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.

105. The C-Qur Mesh failed to perform as safely as an ordinary consumer and/or his physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the C-Qur mesh outweigh its benefits. The design defects in the C-Qur mesh were not known, knowable and/or reasonably visible to Plaintiff and/or his physician or discoverable upon any reasonable examination. The C-Qur mesh was used and implanted in the manner in which it was intended to be used and implanted by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.

106. The defective and unreasonably dangerous condition of the C-Qur Mesh was the proximate cause of the damages and injuries complained of by Plaintiff.

107. As a direct and proximate result of the C-Qur Mesh's aforementioned design defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT III
STRICT LIABILITY – MANUFACTURING DEFECT

108. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

109. Defendants supplied, manufactured, packaged, sold, distributed and/or otherwise placed into the stream of commerce the C-Qur mesh implanted in Plaintiff. The C-Qur mesh was defective in its manufacture and construction when it left the hands of Defendants in that its manufacture, construction and packaging deviated from good manufacturing practices and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical device manufacturer.

110. The C-Qur Mesh as manufactured and constructed by Defendants was unreasonably dangerous to end consumers including Plaintiff and posed an unreasonable degree of risk, danger and harm to Plaintiff.

111. The C-Qur Mesh was expected to reach and did reach Plaintiff's implanting surgeon and Plaintiff without substantial change in the condition in which it was manufactured, suppled, distributed sold and/or otherwise placed in the stream of commerce.

112. The manufacturing defects in the C-Qur mesh implanted in Plaintiff was not known, knowable or readily visible to Plaintiff's physician or to Plaintiff nor was it discoverable upon any reasonable examination by Plaintiff's physician or Plaintiff. The C-Qur Mesh was used and implanted in the very manner in which it was intended to be used and implanted by Defendant in accordance with the instructions for use and specifications provided by Defendants.

113. The C-Qur Mesh implanted in Plaintiff was different from its intended design and failed to perform as safely as a product manufactured in accordance with the intended design would have performed.

114. The defective and unreasonably dangerous condition of the C-Qur Mesh product was a proximate cause of damages and injuries suffered by Plaintiff.

115. As a direct and proximate result of the C-Qur Mesh's aforementioned manufacturing defect, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT IV
STRICT LIABILITY – FAILURE TO WARN

116. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

117. Defendants manufacture, design, market, sell and/or otherwise place into the stream of commerce their C-Qur mesh.

118. The Defendants failed to properly and adequately warn and instruct Plaintiff and his treating physician that C-Qur mesh was designed and/or manufactured in a way that could cause injuries and damages including lasting and permanent injuries. Defendants further failed to inform and further warn Plaintiff and his treating physician with respect to the most effective proper technique and methods of implantation and/or the selection of appropriate candidates to receive C-Qur Mesh.

119. The Defendants failed to properly and adequately warn and instruct Plaintiff and his treating physician as to the risks of the Defendants' C-Qur Mesh. To the contrary, Defendants withheld information from Plaintiff and his treating physician regarding the true risks as relates to implantation of their C-Qur mesh.

120. The Defendants failed to properly and adequately warn and instruct Plaintiff and

his treating physician that inadequate research and testing of the C-Qur Mesh was done prior to C-Qur mesh being placed on the market and in the stream of commerce and that Defendants' lacked a safe, effective procedure for removal of the C-Qur Mesh once complications from same arise.

121. The Defendants intentionally, recklessly, and maliciously misrepresented the efficacy, safety, risks, and benefits of C-Qur Mesh, understating the risks and exaggerating the benefits in order to advance their own financial interest, with wanton and willful disregard for the rights, safety and health of Plaintiff.

122. Plaintiff and his physicians were unaware of the defects and dangers of C-QUR Mesh, and were unaware of the frequency, severity and duration of the risks associated with the C-QUR Mesh.

123. If Plaintiff and/or his physicians had been properly warned of the defects and dangers of C-QUR Mesh, and of the frequency, severity and duration of the risks associated with the C-QUR Mesh, Plaintiff would not have consented to allow the C-QUR Mesh to be implanted in his body, and Plaintiff's physicians would not have implanted the C-QUR Mesh in Plaintiff.

124. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the C-Qur Mesh, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT V
BREACH OF EXPRESS WARRANTY

125. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

126. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce C-Qur Mesh.

127. In advertising, marketing and otherwise promoting C-Qur Mesh to physicians, hospitals and other healthcare providers, Defendants' expressly warranted that their C-Qur Mesh was safe for use. In advertising, marketing and otherwise promoting C-Qur Mesh, Defendants' intended that physicians, hospitals and other healthcare providers rely upon their representations in an effort to induce them to use C-Qur Mesh for their patients.

128. With respect to Plaintiff, Defendants intended that C-Qur Mesh be implanted in Plaintiff by his treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.

129. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public including Plaintiff that C-Qur Mesh was safe and fit for use by consumers including Plaintiff, that it was of merchantable quality, that its risks, side effects and potential complications are minimal and are comparable to other hernia mesh products that it was adequately researched and tested and was fit for its intended use. Plaintiff and his physicians and healthcare providers relied upon these express representations and warranties made by Defendants and consequently, Plaintiff was implanted with Defendants' C-Qur Mesh.

130. Defendants breached express representations and warranties made to Plaintiff and his physicians and healthcare providers with respect to the C-Qur Mesh implanted in Plaintiff including the following particulars:

a. Defendants represented to Plaintiff and his physicians and healthcare providers through labeling, advertising, marketing materials, detail persons,

seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' C-Qur Mesh was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using C-Qur Mesh;

b. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' C-Qur Mesh was as safe and/or safer than other alternative procedures and devices then on the market, meanwhile Defendants fraudulently concealed information that demonstrated that C-Qur Mesh was not safer than alternative therapies and products available on the market; and

c. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' C-Qur Mesh was more efficacious than other alternative procedures, therapies and/or devices, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of C-Qur Mesh.

131. At the time of making such express warranties, Defendants knew or should have known that Defendants' C-Qur Mesh does not conform to the express warranties and Defendants' acts were motivated by financial gain while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety so as to warrant the imposition of punitive damages.

132. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal

relationships, and other damages.

COUNT VI
BREACH OF IMPLIED WARRANTIES

133. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

134. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' C-Qur Mesh.

135. At all relevant times, Defendants intended that their C-Qur Mesh be implanted for the purposes and in the manner that Plaintiff's implanting surgeon did in fact implant it in accordance with the instructions for use and product specifications provided by Defendants and Defendants impliedly warranted that their C-Qur Mesh was of merchantable quality, safe and fit for its intended use of implantation in Plaintiff and was properly and adequately tested prior to being placed in the stream of commerce.

136. Defendants were aware that consumers such as Plaintiff would be implanted with C-Qur Mesh by their treating physicians in accordance with the instructions for use and product specifications provided by Defendants Plaintiff's physicians. Plaintiff was a foreseeable user of Defendants' C-Qur Mesh and plaintiff was in privity with Defendants.

137. Defendants breached implied warranties with respect to the C-Qur Mesh including the following particulars:

a. Defendants represented to Plaintiff and his physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' C-Qur Mesh was of merchantable quality and safe when used for

its intended purpose meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using C-Qur Mesh;

b. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' C-Qur Mesh was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendants fraudulently concealed information, which demonstrated that the C-Qur Mesh was not safe, as safe as or safer than alternatives and other products available on the market; and

c. Defendants represented to Plaintiff and his physicians and healthcare providers that the Defendants' C-Qur Mesh were more efficacious than other alternative procedures and/or devices, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of C-Qur Mesh.

138. In reliance upon Defendants' implied warranty, Plaintiff's implanting surgeon used C-Qur Mesh to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.

139. Defendants breached their implied warranty to Plaintiff in that the Defendants' C-Qur Mesh was not of merchantable quality, safe and fit for its intended use nor was it adequately tested prior to being placed in the stream of commerce.

140. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety, so as to warrant the

imposition of punitive damages.

141. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT VII
VIOLATION OF CONSUMER PROTECTION LAWS

142. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

143. Plaintiff by and through his treating physician was implanted with Defendants' C-Qur Mesh for the sole, primary and personal use and purpose of treating his physical medical condition and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

144. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or otherwise been implanted with C-Qur Mesh, and would not have suffered permanent physical injury as described herein and incurred medical costs and expenses.

145. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for C-Qur Mesh that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

146. Defendants engaged in unfair methods of competition and/or deceptive acts or practices that were prescribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses,

benefits or qualities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

147. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' C-Qur Mesh. Each aspect of Defendants' conduct combined to artificially create sales of Defendants' C-Qur Mesh.

148. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, marketing and sale of surgical mesh products.

149. Defendants' deceptive, unconscionable and/or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of state and federal consumer protection statutes listed.

150. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of federal and state consumer protection statues, as listed below.

151. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations within the meaning of the following statutes:

a. Maine Unfair Trade Practice Act (Me. Rev. Stat. tit. 5, §§ 205-A-214)

b. 15 U.S.C. §§ 2301-2312 (1982)

152. Under the statutes listed above to protect consumers against unfair, deceptive,

fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

153. Defendants violated the statutes that were enacted in Maine to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' C-Qur Mesh was fit to be used for the purpose for which it was intended while in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

154. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in Maine and other states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

155. Defendants had actual knowledge of the defective and dangerous condition of Defendants' C-Qur Mesh and failed to take any action to cure such defective and dangerous conditions to the detriment of Plaintiff and other consumers.

156. The medical community including Plaintiff's physician and other health care providers relied upon Defendants' misrepresentations and omissions in determining whether to use Defendants' C-Qur mesh.

157. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

158. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

159. As a direct and proximate result of Defendants' violations of the Maine consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

COUNT VII
PUNITIVE DAMAGES

160. Plaintiff re-alleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows:

161. At all times relevant hereto, Defendants knew or should have known that C-Qur Mesh was inherently more dangerous with respect to the risks of foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

162. At all times material hereto, Defendants attempted to misrepresent and did intentionally and knowingly misrepresent facts concerning the safety of their C-Qur Mesh product to Plaintiff, his implanting surgeon, the FDA, the medical community, and the public at large.

163. Defendants' misrepresentation included knowingly withholding material information from Plaintiff, his implanting surgeon, the FDA, the medical community, and the public at large concerning the safety and efficacy of the C-Qur Mesh which deprived Plaintiff and his implanting physician with vitally necessary information with which to make a fully informed decision about whether to use C-Qur mesh in his care and treatment.

164. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that the Defendants' C-Qur Mesh can cause debilitating and potentially life-

threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment.

165. At all times material hereto, Defendants knew and recklessly and/or intentionally disregarded the fact that C-Qur Mesh can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise Plaintiff, his implanting surgeon, the FDA, the medical community, and the public at large of the same.

166. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the risk of injuries and the rate of complication caused by and associated with C-Qur Mesh to Plaintiff, his implanting surgeon, the FDA, the medical community, and the public at large.

167. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true defective nature of C-Qur Mesh with its increased risk of side effects and serious complications, Defendants continue to aggressively market C-Qur Mesh to the medical community and to consumers, including Plaintiff, without disclosing the true risk of such complications and side effects.

168. At the time Plaintiff was implanted with C-Qur Mesh and since that time, Defendants knew that C-Qur Mesh was defective and unreasonably dangerous but continued to manufacture, produce, assemble, market, distribute, and sell C-Qur Mesh so as to maximize sales and profits at the expense of the health and safety of patients, including Plaintiff, in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by C-Qur Mesh to members of the public including Plaintiff.

169. At all times material, Defendants have concealed and/or failed to disclose to

Plaintiff, his implanting surgeon, the FDA, the medical community, and the public at large, the serious risks and the potential complications associated with C-Qur Mesh in order to ensure continued and increased sales and profits to the detriment of the public including Plaintiff.

170. Defendants conduct, acts and omissions as described herein are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law.

171. Defendants' outrageous actions as described herein were performed willfully, intentionally, and with malice in their disregard for the rights of the Plaintiff and the general public.

172. Plaintiff is entitled to punitive damages because the Defendants' breaches of their duties to Plaintiffs were deliberate, intentional, and/or motivated by malice or ill will to Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for Plaintiff's injuries and damages, both past and present;
2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of Plaintiff's injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income or wages, loss of earning capacity, permanent disability, including permanent instability and loss of balance, pain and suffering, and loss of consortium;

3. Punitive damages as allowed by law;

4. Double or triple damages as allowed by law;

5. Attorneys' fees, expenses, and costs of this action;

6. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

7. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: November 15, 2019

Respectfully submitted,

/s/ Kevin M. Fitzgerald

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